

**Serial No. 09/973,609****Docket No. SHE-6144****REMARKS****RECEIVED  
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Claims 21-28, 51, 52 and 61-70 are currently pending in the subject application, and are presently under consideration. Claims 21-28, 51, 52 and 61-70 are rejected. Claims 51 and 62 have been amended. Favorable reconsideration of the application is requested in view of the amendments and comments herein.

**I. Interview Summary**

Applicant's representative thanks the Examiner for the courtesy extending during recent telephone interviews on October 31, 2006. During the interview claim 51 was discussed relative to U.S. Patent No. 5,370,685 to Stevens. While no specific agreement was reached regarding the allowability of any claims, the Examiner expressed an understanding and willingness to reconsider the present application in view of the amendments contained herein. Additionally, during the interview, the Examiner formulated a new interpretation of Stevens - contending that a bracer (70) shown in described in Stevens corresponds to the body portion of claim 51, and that a device capsule (14) corresponds to the cylindrical member being claimed. However, the Examiner still agreed that the claim amendments, reciting that the opening of the cylindrical member is spaced longitudinally apart from the body portion, provide a system that is not taught or suggested in Stevens in view of this new interpretation. Accordingly, this response is written based upon the suggestions of the Examiner made during the above-mentioned telephone interview in an effort to place the application in condition for allowance.

**II. Rejection of Claims 21, 51, 61-63, 67, 70 Under 35 U.S.C. §102(b)**

Claims 21, 51, 61-63, 67 and 70 stand rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,370,685 to Stevens ("Stevens"). Withdrawal of this rejection is respectfully requested for at least the following reasons.

The Office Action contends that claim 51 is anticipated by structure shown and described in Stevens at FIGS. 7-10. In particular, the Office Action alleges that an introducer channel (50) corresponds to the claimed cylindrical member and that a device capsule (14) corresponds to the claimed body portion. However, as discussed in the above-mentioned interview, the introducer

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channel does not extend from the device capsule to terminate in the opening, as claimed, nor is any prosthesis mounted within the introduce channel (50) of Stevens consistent with claim 51. That is, in contrast to the Office Action and the teachings of Stevens, amended claim 51 recites that the opening [of the elongated cylindrical member] is spaced longitudinally apart from the body portion and the prosthesis is mounted within the cylindrical member. Additionally, the interpretation of Stevens applied in the Office Action also fails to teach that the pusher disc (60) is operative to traverse part of the cylindrical member and urge the prosthesis from the cylindrical member through the opening, as recited in claim 51. Instead, the pusher disc (60) of Stevens is shown and described as traversing the larger diameter device capsule (14) in which a prosthetic valve device is situated. Accordingly, claim 51 is not anticipated by Stevens.

As mentioned above, the Examiner telephone Applicant's representative and suggested an alternative interpretation that allegedly read on previously presented claim 51 and claim 62. In particular, as understood from the telephone interview mentioned above, the Examiner contended that expandable bracer 70 could correspond to the claimed body portion and the device capsule (14) could correspond to the claimed cylindrical member. The amendments noted above have been made to make explicit that which was believed implicit in such claims; namely, that the opening of the cylindrical member is spaced longitudinally apart from the body portion. This is in sharp contrast from the bracer (70) of Stevens which is positioned at the opening in a generally circumscribing relationship to the end of the device capsule (14). Accordingly, claim 51 is patentable over Stevens, and allowance of claim 51, 52 and 21-28 and 61 is respectfully requested.

Claim 62 is patentable for substantially the same reasons as claim 51. Accordingly, reconsideration and allowance of claim 62 and claims 63-70 are respectfully requested.

### **III. Rejection of Claim 52 Under 35 U.S.C. §103(a)**

Claim 52 stands rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,370,685 to Stevens ("Stevens") in view of U.S. Patent No. 5,851,210 to Torossian ("Torossian"). Withdrawal of this rejection is respectfully requested for at least the following reasons.

First, it is respectfully submitted that there is no proper motivation or suggestion to

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combine Torossian with Stevens, as suggested in the Office Action. Specifically, Stevens relates to implantation of an expandable heart valve prosthesis, whereas Torossian relates to a stent delivery system and method which does not involve implantation of a heart valve. It is submitted that there is no suggestion in the art to use the stent delivery system of Torossian in combination with implanting a heart valve. For example, such a proposition fails to appreciate the potential complexities associated with the combination of the implanter and heart valve prosthesis recited in claim 52. Therefore, the rejection appears to be based on improper hindsight in which the instant application provides the missing teaching or motivation to combine Torossian and Stevens in the manner suggested in the Office Action.

Assuming *arguendo* that Torossian is combined with Stevens, as suggested in the Office Action, it is respectfully submitted that the combination still fails to teach or suggest the subject matter recited in claim 52. In particular, since claim 51 is individually patentable over Stevens, alone as well as in combination with other art of record for the reasons stated herein above, claim 52 which depend respectively from claims 51 is also allowable (See, *e.g.*, sections II *supra.*). Additionally, nothing in the Torossian patent or in Stevens suggests or provides motivation to one of ordinary skill in the art to utilize the markers of Torossian on the type of implanter configured as recited in claim 51. For this reason, an individual reasonably skilled in the art would not consider the subject matter recited in claim 52 obvious in light of prior art, namely the combination of Torossian and Stevens

For the reasons described above, claim 52 should be patentable over the cited art. Accordingly, withdrawal of this rejection is respectfully requested.

### **III. Rejection of Claims 22-26, 65, 66, 68 and 69 Under 35 U.S.C. §103(a)**

Claims 22-26, 65, 66, 68 and 69 stand rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,370,685 to Stevens ("Stevens") in view of U.S. Patent No. 6,077,296 to Shokoohi, et al. ("Shokoohi"). Withdrawal of this rejection is respectfully requested for at least the following reasons.

The addition of Shokoohi et al. does not cure the deficiencies of Stevens. First, it is respectfully submitted that there is no proper motivation or suggestion to combine Shokoohi et al. with Stevens, as suggested in the Office Action. Specifically, Stevens relates to implantation

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of an expandable artificial heart valve prosthesis, whereas Shokoohi et al. relates to an endoluminal vascular prosthesis that does not include a heart valve. It is submitted that there is no suggestion to use the wire support of Shokoohi et al. in combination with a prosthetic valve device as taught by Stevens. For example, such a proposition fails to appreciate the potential complexities associated with the combination of implanter and heart valve prosthesis recited in claim 51. Therefore, the rejection appears to be based on improper hindsight in which the instant application provides the missing teaching or motivation to combine Shokoohi et al. and Stevens in the manner suggested in the Office Action.

Assuming *arguendo* that Shokoohi et al. is combined with Stevens, as suggested in the Office Action, it is respectfully submitted that the combination still fails to teach or suggest the subject matter recited in claims 22-26. As mentioned above, Stevens, alone or in combination with Shokoohi et al. or any other cited reference, still fails to teach or suggest the structural and functional interrelationships of claim 51 from which claims 22-26 depend. Shokoohi et al. further includes no teaching or suggestion that would enable one of ordinary skill in the art to mount a valve in the support taught by Shokoohi et al., as recited in claims 22-26. Claims 65, 66 and 68, which depend from claim 62, are patentable for at least substantially the same reasons, and their allowance is respectfully requested.

#### **IV. Rejection of Claim 27 Under 35 U.S.C. §103(a)**

Claim 27 stands rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,370,685 to Stevens ("Stevens") in view of U.S. Patent No. 5,549,665 to Vesely, et al. ("Vesely"). Withdrawal of this rejection is respectfully requested for at least the following reasons.

The Office Action contends that it would be obvious to use a cloth covering (35) as taught by Vesely in the prosthetic valve device of Stevens. However, the addition of Vesely does not cure the deficiencies of Stevens, as discussed above. Additionally, the reasons for motivation of the cloth covering appear based on improper hindsight or based on unsupported assertions not supported in the references. Accordingly, claim 27 should be patentable over the cited art. Accordingly, withdrawal of this rejection is respectfully requested.

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**V. Rejection of Claim 28 Under 35 U.S.C. §103(a)**

Claim 28 stands rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,370,685 to Stevens ("Stevens"). Withdrawal of this rejection is respectfully requested for at least the following reasons.

Significantly, the Office Action admits that Stevens fails to disclose the use of a pulmonic animal heart valve, as recited in claim 28. Without the benefit of any prior art teaching, the Office Action then goes on to conclude that it would have been obvious matter of design choice to modify the type of valve used in Stevens to a pulmonic valve. Applicant submits that a heart valve prosthesis and implant combination recited in claim 28, including a pulmonic valve, has structural and functional features (*e.g.*, generally soft and substantially thin cusps), which, for certain applications, has a propensity for improved valve function and longevity, when compared to many other types of valves (*e.g.*, as disclosed in Stevens). These advantages, which the Court of Appeals for the Federal Circuit mandates must be considered, demonstrate non-obviousness of claim 28 over Stevens and the approaches disclosed in the other art of record. *In re Chu*, 34 U.S.P.Q.2d 1089 (Fed Cir 1995). Applicant submits that the absence of any teaching of employing a pulmonic valve in the type of heart valve prosthesis being claimed in claim 28 further weighs on the side of non-obviousness, as it demonstrates the failure of those skilled in the art to appreciate the potential benefits of using a pulmonic valve in the combination of claim 28. See, for example, *Arkie Lures Inc. v. Gene Larew Tackle Inc.*, 43 U.S.P.Q.2d 1294, 1297 (Fed. Cir. 1997), where the Court held that when elements have co-existed for many years and never combined weighs on the side of non-obviousness. Similar to the situation in *Arkie Lures*, *supra*, the combination of claim 28 further represents a solution to a problem (an easily implanted, competent heart valve prostheses) for which there is long felt but unmet need. This becomes clearer when the teachings of Stevens are considered as a whole.

The Office Action further asserts that one of ordinary skill in the art "would have expected Applicant's invention to perform equally well with the type of valve chosen as taught by Stevens such that it corresponds to the one being replaced or the claimed pulmonic valve in claim(s) 28 because both heart valve prostheses perform the same function..." If the rejection of claim 28 is maintained, Applicant respectfully requests that the Examiner identify a legal basis

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(statute, rule or legal precedent) to support how an expectation of one skilled in the art about the performance of the combination recited in claim 28, if the structure of claim 28 were modified to use a valve taught by Stevens, would affect patentability of claim 28. This contention appears to rely explicitly on improper hindsight to support an obviousness conclusion.

For the reasons described above, claim 28 should be patentable over the cited art. Accordingly, withdrawal of this rejection is respectfully requested.

**VI. Rejection of Claim 64 Under 35 U.S.C. §103(a)**

Claim 64 stands rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,370,685 to Stevens ("Stevens") in view of U.S. Patent No. 5,733,267 to Del Toro ("Del Toro"). Withdrawal of this rejection is respectfully requested for at least the following reasons.

The Office Action relies on Del Toro for a purported teaching of a handle. Contrary to the contention in the Office Action, Del Toro, does not teach a handle portion attached to the body portion at a position near a substantially opposite end of the body portion from which the cylindrical member extends, as recited in claim 50. Instead, Del Toro discloses a manifold stabilizer 40 (not a handle) that operates to hold the inner shaft 36 in position during pull back of a middle pull back shaft 34 to further prevent flattening of the outside the body arc or the inside the body arc during deployment (Del Toro at Col. 3, lines 17-29). Moreover, there is no motivation to add such a stabilizer 40 to any part of the device taught in Stevens, especially not extending from either the bracer (70) of Stevens or from the device capsule (14), which the Examiner has interpreted as could correspond to the body portion recited in claim 62. Such a contention would require inserting the alleged stabilizer (40) into the implantation site since Stevens, however, discloses both such parts as being used in endovascular valve replacement, such that there would be no motivation to include any handle or include a stabilizer, as taught by Del Toro. Stevens at Col. 4, line 59, through Col. 5, line 28.

For the reasons described above, claim 64 is patentable over the cited art. Accordingly, withdrawal of this rejection is respectfully requested.

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In view of the foregoing remarks, Applicant respectfully submits that the present application is in condition for allowance. Applicant respectfully requests reconsideration of this application and that the application be passed to issue.

If the Examiner has any questions or if the Applicant or its representative can be of any assistance in connection with prosecution of this application, the Examiner is invited and encouraged to contact the undersigned at the number identified below.

Please charge any deficiency or credit any overpayment in the fees for this amendment to our Deposit Account No. 20-0090.

Respectfully submitted,



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